UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,790	12/19/2003	Christopher C. Fraser	MP100-535OMNICN1M	6648

30405 7590 01/30/2007

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/741,790	FRASER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-103* is/are pending in the application.

4a) Of the above claim(s) *93, 94, 102 and 103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-92 and 95-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *86-103* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 86-92 and 95-101, directed to SEQ ID NO:419; and the species election of "radioactive material", filed on 22 December 2006 is acknowledged. The traversal is regarding the restriction requirement between SEQ ID NO:417 and 419, and is on the ground(s) that the only difference between the two sequences is a 33 amino acid signal peptide as SEQ ID NO:417 corresponds to the full length form of TANGO294 (423 amino acids), whereas SEQ ID NO:419 corresponds to the mature form of TANGO294 (390 amino acids), and that a search of both sequences would not place an undue search burden on the examiner. This is persuasive, and restriction requirement between SEQ ID NO:417 and 419 is withdrawn.

Currently, claims 86-103 are pending, and claims 86-92 and 95-101 are under consideration. Claims 93, 94, 102 and 103 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 8/11/2006 is acknowledged and has been considered. A signed copy is attached hereto. Note, since the sequences from the GenBank cited on the IDS (document# C2-C27) are not true publications with a publication date, they are not fully in compliance with 37 CFR 1.97, and thus they will not be printed on the face of the patent issuing from this application.

Drawings

The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures (Figures 1, 2, 7 and 10, for

example), which consist only of nucleic acid or protein sequences (except those showing sequence alignment), which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Appropriate correction is required.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

The specification is objected to because the status of all priority applications is not updated. For example, U.S. Applications 09/578,063 and 09/333,159 have been issued as U.S. Patents 6,764,677 and 7,033,780, respectively; and the rest of the priority applications have been abandoned. Further, in the statement of cross-reference to related applications, the specification states (page 1) "U.S. application serial number 09/596,194, filed on *July 14, 2000*", however, the application 09/596,194 was filed on June 16, 2000.

Appropriate correction is required.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-92 and 95-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The independent claims 86 and 95 recite a cDNA clone EpT294, which was deposited as ATCC Deposit No. 207220. However, while the specification indicates that the clones have

been deposited with the ATCC, and these deposits will be maintained under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (page 351), the specification fails to provide the proper deposit statement, which would satisfy the enablement requirement of 35 U.S.C. 112.

For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository. See MPEP 2404-2410.02.

According to MPEP, if a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claims 86-92 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 86 is directed to an isolated antibody specifically binding to a polypeptide variant of SEQ ID NO:417. To the extent the claims encompass antibodies that bind to epitopes not found in the particularly disclosed sequence.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The limitations of present claim 86 encompasses significant structural dissimilarity of the polypeptide as compared to the disclosed SEQ ID NO:417. The instant specification merely discloses *one* amino acid sequence of SEQ ID NO:417, and no other variants or epitopes thereof or antibodies thereto meeting the limitations of these claims were ever identified or particularly described, and no sequence variations have not been shown to correlate with the biological activity required by the claim. Thus, with the exception of the polypeptide of SEQ ID NO:417 and antibodies thereto, the skilled artisan cannot envision the detailed chemical structure of the encompassed % variants. Therefore, the specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the 90% variants of the polypeptide of SEQ ID NO:417, the epitopes not found in SEQ ID NO:417, or the antibodies thereto.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

The Office, therefore, concludes that SEQ ID NO:417, by itself , is not representative of all variants enconpassed in claim 86, and that to the extent those variants might possess epitopes not found on the disclosed polypeptide, and antibodies to such epitopes have not been described. With the exception of the polypeptide of SEQ ID NO:417 and antibodies thereto, no other variants of the polypeptide or antibodies thereto meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Blanchard et al. (US 5,807,726, provided by applicants) discloses a polypeptide of a dog gastric lipase (column 2, lines 29-37), which amino acid sequence of SEQ ID NO:3 comprises amino acids 37-407 of the present SEQ ID NO:417 with 56.5% sequence similarity (see computer printout of the search results).

Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84, provided by applicants) a polypeptide of a human lysosomal acid lipase, which amino acid sequence (Figure 4) comprises amino acids 15-409 of the present SEQ ID NO:417 with 61% sequence similarity (see computer printout of the search results).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/18/07